

1. Status of the claims

With entry of the present amendment, claim 36 has been canceled, claim 40 has been added, and claims 37-39 have been amended.

Claim 37 has been amended to recite a method of inhibiting the pathological proliferation of ovarian cancer cells in a patient. The amendment to the claim adds no new matter. Support for the amendment can be found, *e.g.*, in the claims as originally filed. Claims 38 and 39 have been amended to provide appropriate dependency and to correct an inadvertent error in the numbering of claim 39.

New claim 40 recites a method of identifying a compound that inhibits the activity of PIK3CA in an ovarian cancer cell that overexpresses PIK3CA, the method comprising contacting the ovarian cancer cell with a compound that inhibits PIK3CA and detecting a decrease in PIK3CA activity in the ovarian cancer cell. This amendment adds no new matter. Support for the amendment can be found in the specification, *e.g.*, on page 22, lines 1-4 and page 31, lines 6-28.

2. Rejections under 35 U.S.C. 112, first paragraph

Claims 36-38 were rejected as allegedly not described in the specification in such a way as to reasonably convey that the application had possession of the claimed invention. The rejection alleges that the specification does not disclose a representative number of species of the PI-kinase inhibitors that function to decrease cell proliferation of ovarian cells such that a common structural feature of a PI-kinase inhibitory compound is evident from the specification.

Applicants respectfully traverse. Applicants are not required to disclose a large number of PI kinase inhibitor that decreases proliferation of ovarian cancer cells, nor is it necessary that the specification provide examples of a particular structure-function/activity relationship to satisfy the written description requirement. What is necessary is that the specification describe in sufficient detail that the skilled artisan can reasonably conclude the inventor had possession of the claimed invention, *i.e.*, that the inventor has identified a method of inhibiting the pathological proliferation of ovarian cancer cells by administering an inhibitor of PI kinase. As acknowledged by the Examiner, the specification provides the first teaching

that correlates the inhibition of PI-kinase activity with decreased pathological proliferation of ovarian cancer cells. Moreover, the specification provides guidance, without undue experimentation, for the artisan to functionally identify PI-kinase inhibitors for use in the claimed methods.

The specification provides a description of a number of inhibitors of PI Kinase including nucleic acids, polypeptides, and non-peptidic inhibitors in the specification, *e.g.*, on page 22, lines 13-26 and page 23, line 23 through page 24, line 13. Although the mechanism by which these agents inhibit PI Kinase differ, they all target PI Kinase polynucleotides or polypeptides. Furthermore, the specification provides examples of assays to detect inhibitors of PI kinase activity, *e.g.*, on page 31, lines 8-28 and assays to assess cellular proliferation and viability of ovarian cancer cells, *e.g.*, page 32, lines 3-17 that have been treated with PI kinase inhibitors. Lastly, the specification provides description of administration of such compounds (*see, e.g.*, page 24, line 7 through page 25, line 12). Accordingly, the specification provides sufficient description for the skilled artisan to identify PI kinase inhibitors that inhibit pathologic proliferation of ovarian cancer cells and to administer those compounds as claimed. Applicants therefore respectfully request withdrawal of the rejection.

Claims 36-39 were rejected as alleged lacking enablement. The rejection alleges that there is no evidence that the *in vitro* results are predictable when extrapolated to and *in vivo* environment and that it would require undue experimentation to practice the methods of the claimed invention. Applicants respectfully traverse.

In determining whether undue experimentation is required to practice the claimed invention, factors such as the amount of guidance presented in the specification and the presence of working examples must be considered (*see, Ex Parte Forman*, 230 USPQ 546 (Bd. Patent App. & Int. 1985) and *In re Wands*, 8 USPQ2d 1400 (Fed. Circ 1988)). As described in *Wands*, "a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should precede" (*see, Wands*, 8 USPQ2d at 1404, quoting *In re Jackson*, 217 USPQ 804 (Bd. Pat. App. & Int. 1982)). Applicants have provided sufficient teaching and examples to enable the skilled artisan to identify PI kinase inhibitors that inhibit pathologic proliferation of ovarian cancer cells and to administer such

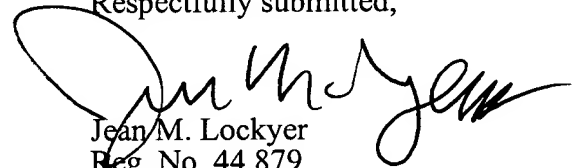
compounds to a patient. As described above, the specification discloses various types of PI kinase inhibitors and assays to measure PI activity and cellular proliferation and viability. Thus, the specification provides routine assays to be used in identifying the compounds to be used in practicing the methods of the invention and provides guidance for the direction in which any experimentation should proceed. Additional evidence that the teachings in the specification support the *in vivo* practice of the methods can be provided to the Examiner by Declaration if required. Applicants therefore respectfully request withdrawal of the rejection.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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